APR 2 7 2004

K033505

RENACLEAN™ SH DIALYZER CLEANING SYSTEM

510(k) Summary of Safety and Effectiveness

Manufacturer: Minntech Corporation
Address: 14605 28th Avenue North
Mpls, MN 55447
USA

Official Contact: Craig Smith
Vice President, Regulatory Affairs and Quality Assurance

Minntech Corporation has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalency of the Renaclean™ SH Dialyzer Cleaning System to other dialyzer pre-cleaning cycles in automated dialyzer reprocessing systems currently in distribution in the United States.

1. Device Description

The Renaclean SH Dialyzer Cleaning System facilitates the cleaning and removal of blood and other debris from multiple-use hollow fiber dialyzers prior to reprocessing on a Renatron® Dialyzer Reprocessing System. The stand-alone countertop system utilizes ANSI/AAMI quality water and a pre-diluted sodium hypochlorite solution.

The operator, through the use of a membrane switch front panel, controls the Renaclean SH Dialyzer Cleaning System. Operators have the following cycle choices: High Flux dialyzer clean, Low Flux dialyzer clean and System Sanitize.

2. Intended Use

Minntech Corporation's Renaclean SH Dialyzer Cleaning System is used to facilitate the cleaning of blood and other debris from multiple-use hollow fiber dialyzers, prior to being reprocessed on a Renatron Dialyzer Reprocessing System.

3. Comparison to Another Device in Commercial Distribution Within the United States

The Renaclean SH Dialyzer Cleaning System is equivalent to other dialyzer pre-cleaning cycles in automated dialyzer reprocessing systems currently in distribution in the United States. The Renatron II Dialyzer Reprocessing System (K904210) pre-clean cycle is intended to pre-clean multiple-use dialyzers prior to testing and sterilization.

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4. Summary

4.1 Minntech Corporation has performed functional testing to show the Renaclean Dialyzer Cleaning System is safe and has equivalent performance with respect to the predicate device.

4.2 All materials have been tested for material compatibility with the chemicals used in the system as specified in the labeling.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information within the 510(k) to support the claim that the Renaclean Dialyzer Cleaning System is safe and effective when used in accordance with the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2004

Mr. Richard M. Ormsbee
Senior Regulatory Affairs Specialist
MINNTECH®
14605 28th Avenue, N.
MINNEAPOLIS MN 55447

Re: K033505
Trade/Device Name: Renaclean™ SH Dialyzer Cleaning System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LIF
Dated: February 4, 2004
Received: April 5, 2004

Dear Mr. Ormsbee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K033505

Device Name: RenaClean™ SH Dialyzer Cleaning System

Indications for Use:

Minntech Corporation's RenaClean™ SH Dialyzer Cleaning System is used to facilitate the cleaning of blood and other debris from multiple-use hollow fiber dialyzers, prior to being reprocessed on a Renatron® Dialyzer Reprocessing System.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per21 CFR 801.109) OR Over-the Counter-use ___ (Optional Format 1-1-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033505